

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN**

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**SEAN REGAN, individually and on behalf  
of all others similarly situated,**

Plaintiff,

-vs-

**Case No. 12-C-758**

**SIOUX HONEY ASSOCIATION  
COOPERATIVE,**

Defendant.

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**DECISION AND ORDER**

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This three-count complaint is a putative class action brought by Sean Regan against Sioux Honey Association Cooperative (“Sioux Honey”), the manufacturer of Sue Bee Clover Honey. In Count II, Regan alleges that the failure to disclose the absence of bee pollen in Sue Bee Clover Honey violates the labeling requirements associated with Wisconsin’s so-called “Honey Standard.” This claim is preempted by the Federal Food, Drug and Cosmetic Act (“FDCA”), as amended by the Nutrition Labeling and Education Act (“NLEA”), 21 U.S.C. § 341 et seq.. The remaining claims are also subject to dismissal as discussed below.

**Preemption: Counts II and III**

With respect to preemption, Sioux Honey moves to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Preemption is an affirmative defense, so the “more appropriate motion would have been one under Rule 12(c)” for judgment on the pleadings because “plaintiffs have no duty to anticipate affirmative defenses.” *S.C. Johnson*

*& Son, Inc. v. Transport Corp. of Am., Inc.*, 697 F.3d 544, 547 (7th Cir. 2012); *see also* *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010). Regan does not object to Sioux Honey’s procedural error, and in any event, the issue of preemption is plainly implicated and even anticipated by the allegations in the complaint. Whatever the correct procedural label, judgment on the pleadings is warranted when “the well-pled facts of a complaint fail to show that the plaintiff is entitled to relief.” *Leimkuehler v. Am. United Life Ins. Co.*, 752 F. Supp. 2d 974, 976 (S.D. Ind. 2010) (discussing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)). If claims are preempted, “dismissal is the proper outcome – but dismissal on the merits, with prejudice like other merits judgments, not dismissal for want of federal jurisdiction.” *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 425 (7th Cir. 2011); *see also* *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 608 (6th Cir. 2004).

The doctrine of preemption is based in the Supremacy Clause, which states, “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the Supreme Law of the land.” U.S. Const., art. VI, cl. 2. There are three types of preemption: express preemption, conflict (or implied) preemption, and field (or complete) preemption. *Hoagland v. Town of Clear Lake, Inc.*, 415 F.3d 693, 696 (7th Cir. 2005). Express preemption occurs when a federal statute “explicitly states that it overrides state or local law.” *Id.* Conflict preemption exists if it would be “impossible for a party to comply with both local and federal requirements or where local law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Id.* (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). Field preemption occurs when

federal law “so thoroughly occupies a legislative field’ as to make it reasonable to infer that Congress left no room for the states to act.” *Id.* (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

The NLEA was passed to “clarify and to strengthen [the FDA’s] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.” *Nat’l Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (10th Cir. 1997). The NLEA provides that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce” any “requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title . . . ” 21 U.S.C. § 343-1(a)(1). With respect to federal “standards of identity,” the Secretary of Health and Human Services has the authority to “promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards or fill of container.” 21 U.S.C. § 341.

There is no federal “standard of identity” for honey. *Guerrero v. Target Corp.*, — F. Supp. 2d —, 2012 WL 3812324, at \*9 (S.D. Fla. Sept. 4, 2012); *see also* Dan Eggen, *Influence Industry: U.S. honey industry asks FDA for national purity standard*, Washington

Post, July 1, 2010.<sup>1</sup> However, Wisconsin has established its own “Honey Standard”<sup>2</sup> which provides that no person may “represent, directly or by implication in connection with the sale, offering for sale, or advertising or distributing for sale of any product, that the product is ‘honey’ unless the product meets the criteria for ‘honey’ described in Part One, Section 3.1 through Part One, Section 4.2 of the *Codex Alimentarius*, number 12-1981 (revised 2001) adopted by the United Nations food and agriculture organization and the World Health Organization.” Wis. Admin. Code § ATCP (Agriculture, Trade & Consumer Protection) 87.015 (Honey Standard); *see also* Wis. Stats. §§ 100.187(1)(a), (3)(a). With respect to the removal of pollen, Part One, Section 3.1 of the Codex provides that “No pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter.” Accordingly, Regan claims that Sioux Honey’s failure to disclose the absence of pollen in Sue Bee Clover Honey violates these labeling requirements. § 100.187(3)(a) (“No person may label a product as honey or imply that a product is honey unless the product meets the standards established under sub. (1)(a)”); § 100.187(1)(a) (DATCP shall promulgate rules that “[e]stablish standards for products sold as honey that are consistent with the standard for honey under the Codex Alimentarius . . .”).

Sioux Honey argues that this claim is preempted by section 403A of the NLEA, which provides, in pertinent part, that states may not establish “any requirement for the labeling of food of the type required by section . . . 343(i)(1) . . . that is not identical to the requirement

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<sup>1</sup> <http://www.washingtonpost.com/wp-dyn/content/article/2010/06/30/AR2010063005309.html>.

<sup>2</sup> A handful of other states have also adopted a Honey Standard, including Florida, North Carolina, California, Nebraska and Utah.

of such section . . .” 21 U.S.C. § 343-1(a)(3). In turn, section 403(i)(1) provides that a food is deemed misbranded unless its label bears “the common or usual name of the food, if any there be . . .” 21 U.S.C. § 343(i)(1). In other words, when (as here) there is no federal standard of identity, the label must bear the “common or usual name” of the food contained therein. Under the applicable regulations, the “common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients.” 21 C.F.R. § 102.5(a). The name “shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.” *Id.* The common or usual name may be established by regulation or common usage. 21 C.F.R. § 102.5(d).

In a nearly identical lawsuit filed against Sioux Honey involving California’s Honey Standard, the court explained that “Sue Bee Clover Honey meets the typical definition of honey found in dictionaries. Webster’s New World Dictionary (3rd Coll. ed. 1998) defines honey as ‘a thick, sweet, syrupy substance that bees make as food from the nectar of flowers and store in honeycombs.’ . . . As Sioux Honey demonstrates in its compendium of state honey statutes, . . . states throughout this nation have similarly defined honey. None of these definitions require that honey contain non-filtered pollen.” *Brod v. Sioux Honey Ass’n, Coop.*, — F. Supp. —, 2012 WL 3987516, at \*8 (N.D. Cal. Sept. 11, 2012). In another California honey lawsuit, the court found that the term “honey” is the “common or usual name for a product where the pollen’s removal was avoidable” because the National Honey

Board<sup>3</sup> “uses the word ‘honey’ without mentioning pollen or stating whether the pollen has been avoidably or unavoidably removed. When defining ‘honey,’ the Board states: Honey is honey, it’s just that simple. A bottle of pure honey contains the natural sweet substance produced by honey bees from the nectar of plants or secretions of living parts of plants. Nothing else.” *Overton v. CVS Caremark Corp.*, No. SACV 12-0982 DOC (ANx), Order Granting Defendants’ Motion to Dismiss, at 12-13 (C.D. Cal. Dec. 11, 2012) (citing The National Honey Board, *Learn about Honey*) (Exhibit A to Reply Brief, ECF No. 19-1). The Court agrees with this analysis and finds that the common or usual name for honey is honey.

Accordingly, while federal law *requires* that Sue Bee Clover Honey be labeled “honey,” Wisconsin law *prohibits* using the label “honey” where the pollen was avoidably removed. *Brod* found that this presents a “classic case of conflict preemption” because it is impossible for Sioux Honey to comply with both state and federal law regarding the labeling of Sue Bee Clover Honey. 2012 WL 3987516 at \*9; *see also Ross v. Sioux Honey Ass’n Coop.*, No. C-12-1645 EMC, 2013 WL 146367 (N.D. Cal. Jan. 14, 2013). While the Court agrees with *Brod*’s reasoning in this regard, the Court will analyze this case under the rubric of express preemption because the NLEA has an express preemption clause that provides as follows: “The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is *expressly preempted* under section 403(A) of the [FDCA].” Pub. L. No.

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<sup>3</sup> The National Honey Board is a “federal research and promotion board under USDA oversight that conducts research, marketing and promotion programs to help maintain and expand markets for honey and honey products.” <http://www.honey.com/about/about-nhb>.

<sup>4</sup> <http://www.honey.com/honey-at-home/learn-about-honey>.

101-535, 104 Stat. 2353, Section 6(c)(1) (emphasis added); *see also Turek*, 662 F.3d at 425. The existence of an express preemption clause does not foreclose “any possibility of implied [conflict] pre-emption.” *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000) (citing *Myrick*, 514 U.S. at 288). Nonetheless, when “Congress has considered the issue of pre-emption and has enacted in the legislation a provision explicitly addressing that issue, and when that provision provides a ‘reliable indicium of congressional intent with respect to state authority,’ ‘there is no need to infer congressional intent to pre-empt state laws from the substantive provisions’ of the legislation.” *Cipollone*, 505 U.S. at 517 (internal citations omitted).

With respect to express preemption, courts focus on the “plain wording of the clause, which necessarily contains the best evidence of Congress’ preemptive intent.” *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). As explained above, the NLEA forbids a state from “directly or indirectly” establishing “any requirement for the labeling of food of the type required by” § 343(i)(1) “that is not *identical* to the requirement of such section . . .” § 343-1(a)(3) (emphasis added). Section 403(i)(1) requires only that the label must bear the “common or usual name of the food, if any there be.” § 343(i)(1). The “common or usual name” of Sue Bee Clover Honey is “honey,” but Wisconsin’s Honey Standard forbids Sioux Honey from using that label. Therefore, Wisconsin’s labeling requirement is preempted because it is not identical to the NLEA’s labeling requirement. *Accord, Overton* at 15 (“Given that . . . the ‘common or usual name’ of a product that has had its pollen avoidably removed is ‘honey,’ and that California Section 29413(e) disallows such a product to be

labeled ‘honey,’ it imposes a requirement which is not imposed by federal law, and is therefore not identical to federal law. Consequently, the California Section 29413(e) is preempted by the NLEA and Plaintiff’s state law claims based on a violation of California Section 29413(e) are also preempted”).<sup>5</sup>

In a case involving Florida’s Honey Standard, the court found that the “provisions of [section 403(i)] are triggered only in the absence of *any* standard of identity, state or federal. . . . [Section 403(g)] expressly states that it only applies to federal standards of identity, whereas [section 403(i)] contains no similar limitation to state or federal standards of identity.” *Guerrero*, 2012 WL 3812324 at \*9-10 (emphasis added). In other words, according to *Guerrero*, if a state has “prescribed a standard of identity for a food product, the provisions of [section 403(i)(1)] are not triggered.” *Id.* at \*10. Respectfully, the Court disagrees with this analysis. Section 403(g) is titled “Representation as to definition and standard of identity.” It applies to a food product “for which a definition and standard of identity has been prescribed by regulations as provided by section 341 . . .” § 343(g). Conversely, section 403(i) is titled “Label where *no* representation as to definition and standard of identity.” § 343(i) (emphasis added). The use of the same language in both provisions – “representation as to definition and standard of identity” – is a clear signal that while section 403(g) applies to products with a federal standard of identity, section 403(i)

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<sup>5</sup> Given the foregoing analysis, the Court must note that it disagrees with the observation in *Brod* that states are not “powerless to act in this arena. For instance, if California required disclosure on its labels that the honey was *e.g.*, ‘filtered’ or ‘pollen free,’ that would appear not to conflict expressly with § 343(i). California simply cannot under § 343(i) ban the use of the label ‘honey’ for products which are commonly and usually called honey.” *Brod*, 2012 WL 3987516 at \*9. To the contrary, such a requirement would be preempted because it is not identical to the federal requirement.



applies to all products that do *not* have a federal standard of identity. This includes products, like honey, that do not have a federal standard, but for which some states (including Wisconsin) have attempted to impose their own local standards. Indeed, the purpose of the NLEA was to “create uniform national standards regarding the labeling of food and to prevent states from adopting inconsistent requirements with respect to the labeling of nutrients.” *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1175 (Cal. 2008). This purpose is not served if states are allowed to displace federal labeling requirements. *Turek*, 662 F.3d at 426 (noting that it is “easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy”). Therefore, the Court concludes that the operation of section 403(i) is not precluded by the enactment of a standard of identity under state law.<sup>6</sup>

In Count III, Regan alleges that by failing to disclose the absence of pollen on the labels for Sue Bee Clover Honey, Sioux Honey was unjustly enriched because they were able to charge a price premium. This claim is essentially the same as Count II, only brought under the guise of state common law. It is preempted for the reasons already stated.

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<sup>6</sup> This position also finds support in the regulatory guidance. *See*, State Petitions Requesting Exemption from Federal Preemption, 58 Fed. Reg. 2462-01, 2463 (Jan. 6, 1993) (“Several comments asked whether a State standard of identity . . . is preempted if it is for a food for which there are no Federal Standards. . . . If there is no Federal standard of identity . . . then there is no basis, under the terms of section 403A(a)(1) of the act, for finding that there is Federal preemption. By contrast, under section 403A(a)(2) through (a)(5) a State may not establish or continue in effect any requirement ‘of the type’ set forth in the sections of the act specified in section 403A(a)(2) through (a)(5). Thus, State or local requirements can be preempted under section 403A(a)(2) through (a)(5) *even if no analogous Federal regulation had been promulgated*”) (emphasis added).

*Cipollone*, 505 U.S. at 521 (“[t]he phrase ‘[n]o requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules”); *Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431, 443 (2005) (in the context of express preemption, “the term ‘requirements’ . . . reaches beyond positive enactments, such as statutes or regulations, to embrace common-law duties”).

### **Count I**

Finally, in Count I, plaintiff alleges that Sioux Honey violated Wisconsin Administrative Code § ATP 90.10(1), which provides that “food sold or distributed for sale in this state shall be labeled in compliance with applicable rules adopted by the United States food and drug administration under 21 CFR 101, 102, 104, 105 and 130.” Specifically, plaintiff alleges that Sioux Honey violated 21 C.F.R. § 102.5(c)<sup>7</sup> because pollen is a “characterizing ingredient or component” of honey. However, it is “well settled . . . that the FDCA creates no private right of action.” *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999); 21 U.S.C. § 337(a) (“all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States”); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 944 (E.D. Wis. 2008) (“Enforcement of the FDCA is permitted exclusively

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<sup>7</sup> “The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) . . . when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food.” 21 C.F.R. § 102.5(c).

‘by and in the name of the United States’ or, in certain circumstances, by a state”). Therefore, a private party cannot attempt to enforce the FDCA “under the guise of state law claims.” *Perez v. Nidek Co.*, 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009); *see also Rikos v. Proctor & Gamble Co.*, 782 F. Supp. 2d 522, 538 n.26 (S.D. Ohio 2011) (“Courts have interpreted section 337(a) as prohibiting private rights of action under the FDCA and have dismissed state law claims that seek to enforce the FDCA or its regulations”); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (“to the extent that these claims are merely derivative of plaintiff’s state law claims, they are not saved merely by being recast as violations of the federal adulteration and misbranding statutes”).

Even if Regan could pursue a private cause of action for violation of § 102.5(c), he fails to state a claim thereunder. Pollen is not a “characterizing ingredient or component” because, as the Court already explained, honey is honey, even in the absence of pollen. *See*, Bruce Boynton, CEO, National Honey Board, *Honey Without Pollen is Still Honey*,<sup>8</sup> April 16, 2012 (“Honey without pollen is still honey nutritionally and in flavor, and that is why the U.S. Department of Agriculture identifies it as such. . . . The truth is that honey is made by honey bees from *nectar* of flowers and plants, not pollen. Pollen grains may end up in the exposed honey in the hive through a number of incidental or accidental ways, but it is not used by honey bees to make honey”) (emphasis in original); *see also Overton* at 13-14 (citing the same article therein). Stated another way, § 102.5(c) does not apply because honey is a “single ingredient” product. *Cf.* Food Additives Permitted for Direct Addition to Food for

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<sup>8</sup> <http://www.honey.com/honey-industry/honey-and-bee-research/honey-without-pollen-is-still-honey>.

Human Consumption; Sucralose, 63 Fed. Reg. 16417-01, 16431 (April 3, 1998) (“Sucralose is a single ingredient and has no other characterizing ingredients or components that are added or removed. Thus, § 102.5(c) does not govern the question of what is the appropriate name for this additive”).

**NOW, THEREFORE, BASED ON THE FOREGOING, IT IS HEREBY  
ORDERED THAT:**

1. Sioux Honey’s motion to file a recent decision [ECF No. 20] is **GRANTED**;
2. Sioux Honey’s motion to dismiss [ECF No. 13] is **GRANTED**; and
3. This matter is **DISMISSED**. The Clerk of Court is directed to enter judgment accordingly.

Dated at Milwaukee, Wisconsin, this 31st day of January, 2013.

**BY THE COURT:**

  
**HON. RUDOLPH T. RANDA**  
**U.S. District Judge**